

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)  
Cardiovascular and Renal Drugs Advisory Committee**

**Hilton Washington DC North/Gaithersburg  
Gaithersburg Maryland**

**AGENDA  
April 25, 2006**

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*The committee will discuss new drug application (NDA) 21-359 Cellegesic™ (nitroglycerin [NTG] ointment), 0.4% intra-anal, Cellegy Pharmaceuticals, Inc., for the proposed indication of relief of pain associated with anal fissures*

8:00	Call to Order and Introductions	<b>William R. Hiatt, M.D.</b> Committee Chair Cardiovascular and Renal Drugs Advisory Committee
	Conflict of Interest Statement	<b>LCDR Cathy Groupe, B.S.N.</b> Executive Secretary Cardiovascular and Renal Drugs Advisory Committee
8:10	Introduction and Background	<b>Norman Stockbridge, M.D., Ph.D.</b> Director Division of Cardiovascular and Renal Products FDA Center for Drug Evaluation and Research
8:15		<b>Open Public Hearing</b>
8:45		<b><u>Sponsor Presentation – Cellegy Pharmaceuticals, Inc.</u></b>
	Overview of Phase 1 and Phase 3 Studies	<b>Daniel L. Azarnoff, M.D., F.A.C.P.</b> President, D.L. Azarnoff Associates Professor of Medicine University of Kansas Medical Center
	Pathophysiology of Anal Fissures and Clinical Aspects Of Diagnosis and Treatment	<b>Michael E. Abel, M.D., F.A.C.S., F.A.S.C.S.</b> Assistant Clinical Professor of Surgery University of California at San Francisco Medical School
	Overview of Studies And Regulatory History	<b>Daniel L. Azarnoff, M.D., F.A.C.P.</b>
	Safety	<b>Daniel L. Azarnoff, M.D., F.A.C.P.</b>
	Statistical Methods and Analyses	<b>Robert D. Gibbons, Ph.D.</b> Professor of Biostatistics and Director Center for Health Statistics University of Illinois at Chicago

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**Page 2**

Risk/Benefit

**Jonathan Lund, B.M.B.S., D.M., F.R.C.S.**  
Associate Professor  
School of Medical and Surgical Sciences  
University of Nottingham

Summary and Conclusions

**Thomas Q. Garvey, III, M.D., F.A.C.P.**  
President  
Garvey Associates, Inc.

9:30

**Questions from the Committee**

10:00

**Break**

10:15

**Committee Discussion**

12:00

**Lunch**

1:00

**Committee Discussion**

2:00

**Questions to the Committee**

5:00

**Adjournment**